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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,723	12/15/2005	Richard Einstein	3665-166	5102

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EXAMINER	
AEDER, SEAN E	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,723	EINSTEIN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/15/02*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence comparison*.

DETAILED ACTION

NOTE: It appears that claim 7 is incorrectly drawn to the method of claim 5. For restriction purposes, it is assumed that Applicant intended claim 7 to be drawn to the method of claim 4.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 16, 17, 32 and 33, as specifically drawn to an isolated nucleic acid sequence selected from the group consisting of: (i) the nucleic acid sequence contained in SEQ ID NO: 1-73, 175, 177, 179, 181; (ii) variants thereof, wherein such variants have a nucleic acid sequence that is at least 70% identical to the sequence of (i) when aligned without allowing for gaps; and (iii) fragments of (i) or (ii) having a size of at least 20 nucleotides in length; and a gene comprising a sequence consisting of SEQ ID NOs 74-174, 176, 178, 180, 182-185.
(NOTE: Upon election of group I, Applicant must elect a single nucleic acid SEQ ID NO, as each represents a separate invention and not a species.)

It is noted that the claims of the instant application have been determined to include linking claims. Claim 4 link(s) inventions II-III, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group II, claim(s) 5-6, as specifically drawn to methods detecting a polynucleotide selected from the group consisting of SEQ ID NOs 1-173, 175, 177, 179, 181, or a fragment thereof using nucleic acid sequences that specifically hybridize thereto or using primers that result in the amplification thereof.

(NOTE: Upon election of group II, Applicant must elect a single nucleic acid SEQ ID NO from claim 4, as each represents a separate invention and not a species.)

Group III, claim(s) 7-9, as specifically drawn to methods detecting a polynucleotide selected from the group consisting of SEQ ID NOs 1-173, 175, 177, 179, 181, or a fragment thereof wherein expression of said polynucleotide is detected by assaying for the polypeptide encoded by said polynucleotide.
(NOTE: Upon election of group III, Applicant must elect a single nucleic acid SEQ ID NO from claim 4, as each represents a separate invention and not a species.)

Group IV, claim(s) 10, 11, 14, 32, and 33 drawn to a polypeptide, or a fragment thereof, encoded by a polynucleotide of SEQ ID NO:1-185.
(NOTE: Upon election of group IV, Applicant must elect a single nucleic acid SEQ ID NO from claim 10 or claim 32, as each represents a separate invention and not a species.)

Group V, claim(s) 12, 13, 15, and 18, drawn to a monoclonal antibody that binds to a polypeptide of SEQ ID NO:1-185.
(NOTE: Upon election of group V, Applicant must elect a single nucleic acid SEQ ID NO, as each represents a separate invention and not a species.)

Group VI, claim(s) 19-22, as specifically drawn to a method of treating prostate cancer comprising administering a ligand that specifically binds a gene or RNA comprising a sequence selected from the group consisting of SEQ ID NOS: 1-173, 175, 177, 179, 181, a variant thereof or a fragment of said gene or RNA.
(NOTE: Upon election of group VI, Applicant must elect a single nucleic acid SEQ ID NO, as each represents a separate invention and not a species.)

Group VII, claim(s) 19, 21, 22, 24-31, as specifically drawn to a method of treating prostate cancer comprising administering a ligand that specifically a protein or polypeptide encoded by a gene or RNA comprising a sequence selected from the group consisting of SEQ ID NOs: 1-173, 175, 177, 179, 181, a variant thereof or a fragment of said gene or RNA having a size of at least 20 nucleotides in length, or a polypeptide derived from SEQ ID NOs: 174, 176, 178, 180, and 182-185.
(NOTE: Upon election of group VII, Applicant must elect a single nucleic acid SEQ ID NO, as each represents a separate invention and not a species.)

Group VIII, claim(s) 23, drawn to a method for treating prostate cancer comprising administering a polypeptide of group IV.
(NOTE: Upon election of group VIII, Applicant must elect a single SEQ ID NO from claim 10, as each represents a separate invention and not a species.)

Group IX, claim(s) 34, drawn to a method for screening, identifying, selecting, characterizing, or optimizing biologically active compounds comprising contacting a

candidate compound with a target molecule and determining whether the candidate compound binds said target molecule.
(NOTE: Upon election of group IX, Applicant must elect a single SEQ ID NO from claim 10, as each represents a separate invention and not a species.)

The inventions listed as groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-IX appears to be that they all relate to the special technical feature of a nucleic acid sequence selected from a nucleic acid sequence contained in SEQ ID NO 1 and variants thereof, wherein such variants have a nucleic acid sequence that is at least 70% identical to the SEQ ID NO:1 when aligned without allowing for gaps.

However, Venter et al (US patent 6,812,339; filed 4/14/00) teaches a nucleic acid sequence selected from nucleic acid sequence contained in SEQ ID NO 1 and variants thereof, wherein such variants have a nucleic acid sequence that is at least 70% identical to the SEQ ID NO:1 when aligned without allowing for gaps (see attached sequence comparison of SEQ ID NO: 181090 with instant SEQ ID NO:1).

Therefore, the technical feature linking the inventions of groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 19-22 and 24-31 are generic to a plurality of disclosed patentably distinct species of "**ligands**" comprising the following: ribozymes and antisense oligonucleotides; an antibody; a small molecule; a peptide. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently

added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claim 34 is generic to a plurality of disclosed patentably distinct species of "**target molecules**" comprising the following: a polynucleotide; a polypeptide. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

SHANON A. FOLEY
SUPERVISORY PATENT EXAMINER